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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF UTAH  
CENTRAL DIVISION

LINDA P. SMITH,

*Plaintiff*

v.

XAVIER BECERRA, in his capacity  
as the Secretary of the United States  
Department of Health and Human  
Services,

*Defendant*

Case No. 1:21-cv-00047-HCN

RESPONSE TO ORDER

JURY TRIAL DEMANDED

Judge Howard Nielson, Jr.

Pursuant to this Court's Order of June 24, 2021 (Dkt. #16), Plaintiff Linda Smith states her objection to resolution of this matter as proposed by Secretary.

The Complaint in this case seeks a finding that supplies for Mrs. Smith's diabetes monitoring device (*i.e.*, a "continuous glucose monitor" (CGM)) are covered Medicare benefits for her and an order directing the Secretary to provide coverage of the claims at issue.

Further, as noted in the Complaint, Mrs. Smith's claims were denied on the grounds that Mrs. Smith's CGM allegedly is not "primarily and customarily used to serve a medical purpose" as defined in a ruling issued by CMS (*i.e.*, CMS 1682-R). As noted in the decisions of the ALJ that are the subject of this suit and alluded to by the Medicare Appeals Council (MAC),<sup>1</sup> CMS Rulings are binding on all levels within HHS (including ALJs and the MAC). *See* 42 C.F.R. § 401.108. Accordingly, in addition to the immediate claims at issue, Mrs. Smith's claims will be continued to be denied until CMS 1682-2 is determined to be invalid. As further set forth in the Complaint, CMS 1682-R issued in violation of the notice and comment provisions of the Medicare Act. *See* 42 U.S.C. § 1395hh; *Azar v. Allina Health Services*, 139 S.Ct. 1804 (2019). For this reason, the Complaint also seeks a finding that CMS 1682-R issued illegally and an order setting it aside.

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<sup>1</sup> Mrs. Smith would cite the certified administrative record but the Secretary has failed to comply with the statute (42 U.S.C. § 405(g)) and file/serve the record with the "Answer" filed on June 7, 2021.

The resolution proposed by the Secretary does not provide Mrs. Smith the relief she seeks. For at least two of the denied claims, rather than coverage, the proposed resolution seeks “a remand to the Secretary for ... a determination of whether the sensors should be covered as reasonable and necessary for the operation of the insulin pump.” Thus, the relief Mrs. Smith seeks has not been conceded. Instead, the proposed resolution is merely of continued litigation.

Indeed, as set forth in the Complaint, Mrs. Smith has previously litigated the issue of whether a CGM (and related sensors) are “medically reasonable and necessary” and that decision became final no later than June 25, 2018. Thus, Mrs. Smith alleges the Secretary is collaterally estopped from denying coverage on “medically reasonable and necessary” grounds. Accordingly, the continued litigation proposed by the Secretary is the very thing collateral estoppel exists to avoid.<sup>2</sup>

Further, the resolution proposed by the Secretary does not provide Mrs. Smith the relief she seeks in the form of declaring CMS 1682-R illegally issued and setting it aside. Absent such a declaration by this Court, in addition to her current claims, Mrs. Smith’s future claims will be denied. That is because CMS rulings “are binding

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<sup>2</sup> Collateral estoppel serves the triple purposes of protecting litigants from the burden of relitigating an identical issue, promoting judicial economy by preventing needless litigation, and encouraging reliance on adjudication by preventing inconsistent results. *See Allen v. McCurry*, 449 U.S. 90, 94 (1980); *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 326 (1979).

on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS[.]”

Accordingly, Mrs. Smith opposes the Secretary’s proposal. Mrs. Smith seeks the relief set forth in the Complaint. Further, Mrs. Smith believes that the Court should proceed with briefing as proposed by Mrs. Smith in the proposed schedule.

Dated: June 24, 2021

Respectfully submitted,

PARRISH LAW OFFICES

/s/ James C. Pistorino

James C. Pistorino

*Attorneys for Plaintiffs*